

K033974

FEB - 6 2004

**510(K) SUMMARY OF SAFETY AND EFFECTIVENESS**Submitter

Company: ..... 3M ESPE AG  
Street: ..... ESPE Platz  
ZIP-Code, City: ..... D-82229 Seefeld  
Federal State: ..... Bavaria  
Country: ..... Germany  
Establishment Registration Number ..... 9611385  
Official Correspondent: ..... Dr. Andreas Petermann,  
Manager U.S. Regulatory Affairs  
Phone: ..... 011-49-8152-700 1395  
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E-mail: ..... Andreas.Petermann@mmm.com  
Date: ..... December 18, 2003

Name of Device

Proprietary Name: ..... Hermes Bond  
Classification Name: ..... Resin tooth bonding agent  
Common Name: ..... Dental Adhesive

Predicate Devices

Adper Prompt L-Pop by 3M ESPE ..... K 020946  
RelyX Unicem by 3M ESPE ..... K 020256  
Protemp 3 Garant by 3M ESPE ..... K 033022  
3M ESPE HAUR by 3M ESPE ..... K 010781

Description for the Premarket Notification

Hermes Bond is classified as Resin Tooth Bonding Agent (21 C.F.R. § 872.3200) because it is a device intended to be painted on the interior of a prepared cavity of a tooth to improve retention of a restorative material.

Like Adper Prompt L-Pop, 3M ESPE's well-known and well-established resin bonding agent, Hermes Bond offers the advantages of a simplified bonding procedure, eliminating

the need for a separate etching step. Thus it reduces both possible errors during application and post-operative sensitivity. Additionally, it saves the dentist valuable chair time.

Being based on methacrylate chemistry itself, Hermes Bond is well suited for bonding methacrylate composites. The compatibility to silorane based composites is ensured by the formulation of Hermes Bond which has especially been optimized for this purpose. The acidic methacrylates provide efficient etching of the dental hard tissue and initiation of the polymerization of the silorane-based composite (e.g. "Hermes") at the interface with the adhesive. The blend of co-monomers allows at the same time for the formation of a uniform adhesive film on dentin and enamel, and additional chemical crosslinking between OH-functionalized methacrylates and siloranes.

In fact, the bond strength obtained for Hermes/Hermes Bond is comparable to that of Ad-per Prompt L.-Pop with conventional methacrylate composites.

The comparison for chemistry, performance data and indications for use shows that Hermes Bond is substantially equivalent to the predicate devices.

In summary, it can be concluded that safety and effectiveness requirements for Hermes Bond are completely met.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

FEB - 6 2004

Dr. Andreas Petermann  
Manager, U.S. Regulatory Affairs  
3M ESPE AG  
ESPE Platz  
Seefeld, D-82229  
GERMANY

Re: K033974  
Trade/Device Name: Hermes Bond  
Regulation Number: 21 CFR 872.200  
Regulation Name: Resin Tooth Bonding Agent  
Regulatory Class: II  
Product Codes: KLE and EMA  
Dated: December 18, 2003  
Received: December 22, 2003

Dear Dr. Petermann:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Chiu S. Lin', with a stylized flourish at the end.

Chiu S. Lin, PhD

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known):

Device Name: Hermes Bond

Indications For Use: Bonding between dentin/enamel and silorane based composite filling materials

Bonding between dentin/enamel and methacrylate based composite filling materials

Prescription Use ☒  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)  
Division of Anesthesiology, General Hospital,  
Infection Control, Dental Devices

510(k) Number: 16033974

Page 1 of 1